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10/617,184	07/11/2003	David Frederick Horrobin	P63461US4	3007

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EXAMINER	
WILLIAMS, LEONARD M	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/617,184	HORROBIN, DAVID FREDERICK	
	Examiner	Art Unit	
	Leonard M. Williams	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Status of Claims

The amendment and remarks received 2/24/2006 amending claim 8 to read "...than 3:1..." rather than "...and 3:1..." and adding new claims 20-21 has been entered. The examiner notes the amending of claim 8 does not change the scope or breadth of the claim and as stated by the applicant on page 5 of the remarks is amended only to correct informalities. There are no other amendments to the claims.

Response to Arguments

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Further the example as described by the examiner was to clearly demonstrate that the broad claims of the issued patents encompassed the currently claimed invention.

As there are no other substantive arguments made outside the assertion that the obviousness double patenting rejection is improper hindsight the examiner hereby maintains the ODP and 102(b) rejections over the claims of record and broadens the rejections to include the newly added claims. The newly added claim 20 is a restatement of claim 8 changing the 'consisting of' language to 'consisting essentially of'. Claim 21 is drawn to a method of treatment wherein the disorder is Alzheimer's disease and other dementias. It would be inherent that the identical compounds would have the same properties thus the treatment of Alzheimers disease, other dementias and tardive dyskinesia as set forth in claim 8 with the same compounds would inherently treat Alzheimer's disease and other dementias as stated in claim 21. Further the "964 patent addresses such limitations as stated in the ODP rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8-11, 13-17, and 19-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5120760. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present application are drawn to a method of treatment of a disorder selected from the group consisting of Alzheimer's disease and other dementias, and tardive dyskinesia..." by administering an oil comprising n-3 fatty acids such as eicosapentaenoic acid (EPA) and/or stearidonic acid (SA) in varying amounts with or without the presence of n-6 fatty acids such as gamma-linolenic acid.

US Patent No. 5120760 is drawn to a method of treating tardive dyskinesia comprising administering a composition comprising GLA and higher n-6 series acids, with SA and higher n-3 series fatty acids in effective daily amounts of 10mg and 50g of each acid. There is no necessity inherent in the claims that DHA be present.

Claims 1 and 2 of the Horrobin patent are stated below (US Patent 5120760):

1. A method of treating tardive dyskinesia comprising administering to a patient in need of same an effective amount of a composition comprising an essential fatty acid selected from GLA and higher n-6 series acids with an essential fatty acid selected from stearidonic acid and higher n-3 series acids in effective daily amounts of 10mg and 50g of each acid.

2. The method according to claim 1, wherein the n-6 EFA is selected from GLA, DGLA, and AA and the n-3 EFA is selected from stearidonic acid, EPA 22:5 n-3 and DHA.

Based on the limitations detailed in claims 1 and 2 of the patent above one could prepare a composition that comprised 7g of EPA, 2g of stearidonic acid, and 1g of GLA for a total composition weighing 10g. The EPA would comprise 70% of the composition, the stearidonic acid would comprise 20% of the composition, and the GLA would

comprise 10% by weight of the total composition. The total percentage by weight of the n-3 EFAs would be 90%. The n-3 to n-6 ratio of the aforementioned composition would be 9:1 anticipating the.

Patent '760 claims 1 and 2 do not teach the treatment of Alzheimer's disease but do teach the treatment of tardive dyskinesia.

The present application and patent are commensurate in scope, target the same disorder, and share the same inventor, but do not have the same assignee. An obviousness type double patenting rejection is appropriate.

Claims 8-19 and 21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 4753964. Although the conflicting claims are not identical, they are not patentably distinct from each other because

Claim 1 of the '964 patent is drawn to "A method of treating a warm blooded animal subject to combat or to alleviate effects of presenile or senile dementia, which method comprises administering, either orally or parenterally, to said subject an effective amount of an essential fatty acid or a physiologically acceptable salt thereof".

Claim 2 of the '964 patent is drawn to "A method as claimed in claim 1 to combat or to alleviate effects of Alzheimer's disease."

Claim 3 of the '964 patent is drawn to "A method as claimed in claim 2 wherein said fatty acid or salt thereof is selected from the group consisting of dihomogammalinolenic acid, arachidonic acid, eicosapentaenoic acid, docosahexaenoic

acid, linoleic acid, gammalinoleic acid, alphalinolenic acid, 18:4n-3 and physiologically acceptable salts thereof."

Claim 5 of the '964 patent is drawn to "A method as claimed in claim 2 wherein said essential fatty acid or salt thereof is administered at a rate of 1mg to 200g daily."

As the '964 claims reiterated above demonstrate essential fatty acids of either n-6 or n-3 could be used singly to treat Alzheimer's disease and other dementias and in quantities and ranges encompassing the applicant's invention as currently claimed.

The present application and patent are commensurate in scope, target the same disorder, and share the same inventor, but do not have the same assignee. An obviousness type double patenting rejection is appropriate.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-11 and 13-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Horrobin (US Patent 5120760).

Horrobin teaches, in col. 4 lines 25-37 and claims 1 and 2, methods and preparations of medicaments for treating schizophrenia and/or associated tardive dyskinesia by combining an n-6 EFA (GLA, DGLA, or AA) with an n-3 EFA (stearidinic acid, EPA, 22:5 n-3 or DHA).

Claims 1 and 2 of the Horrobin patent are stated below (US Patent 5120760):

1. A method of treating tardive dyskinesia comprising administering to a patient in need of same an effective amount of a composition comprising an essential fatty acid selected from GLA and higher n-6 series acids with an essential fatty acid selected from stearidonic acid and higher n-3 series acids in effective daily amounts of 10mg and 50g of each acid.

2. The method according to claim 1, wherein the n-6 EFA is selected from GLA, DGLA, and AA and the n-3 EFA is selected from stearidonic acid, EPA 22:5 n-3 and DHA.

Based on the limitations detailed in claims 1 and 2 of the patent above one could prepare a composition that comprised 7g of EPA, 2g of stearidonic acid, and 1g of GLA for a total composition weighing 10g. The EPA would comprise 70% of the composition, the stearidonic acid would comprise 20% of the composition, and the GLA would comprise 10% by weight of the total composition. The total percentage by weight of the n-3 EFAs would be 90%. The n-3 to n-6 ratio of the aforementioned composition would be 9:1 anticipating the "...method of treatment of a disorder selected from the group consisting of Alzheimer's disease and other dementias, and tardive dyskinesia, whereby an oil is administered comprising...." of claim 8, the "...method...wherein said EFA comprises more than 40% of the total fatty acids present" of claim 9, the "...method...wherein said EFA comprises more than 70% of the total fatty acids presents" of claim 10, the "...method...wherein the weight ratio of said EFA to said n-6 EFAs present is 4:1 or more" of claim 11, the "...method...wherein the weight ratio of said EFA to any docosahexaenoic acid (DHA), if present, is not less than 3:1" of claim 13, the "...method...wherein the weight ratio of said EFA to any DHA, if present, is 4:1 or more" of claim 14, the "...method...wherein doses of 10mg to 100g of said EFA are administered daily" of claim 15, the "...method...wherein doses of 100mg to 20g of said

EFA are administered daily" of claim 16, the "...method...wherein doses of 500mg to 10g of said EFA are administered daily" of claim 17, the "...method...wherein the disorder is Alzheimer's disease and other dementias" of claim 18, the "...method...wherein the disorder is tardive dyskinesia" of claim 19, and the "...method of treating..." of claim 20.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8, 12 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Horrobin (US Patent 4753964).

Horrobin teaches in the abstract, a method for the treatment of presenile or senile dementia including Alzheimer's disease by administration of a physiologically acceptable lithium compound and/or an essential fatty acid. In column 2 lines 35-60, Horrobin teaches, that the essential fatty acids include linoleic acid, gamma-linolenic acid, eicosapentaenoic acid, 22:5n-3 and docosahexaenoic acid in quantities of 100mg-200g. Claim 1 of the '964 patent discloses "A method of treating a warm blooded animal subject to combat or to alleviate effects of presenile or senile dementia, which method comprises administering, either orally or parenterally, to said subject an effective amount of an essential fatty acid or a physiologically acceptable salt thereof" anticipating the "...method of treatment of a disorder selected from the group consisting of Alzheimer's disease and other dementias, and tardive dyskinesia, whereby an oil is administered comprising...." of claim 8, the "...method of treatment...wherein said n-6 EFAs are absent" of claim 12, and the "...method of treatment...wherein the disorder is Alzheimer's disease and other dementias" of claim 21.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M. Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LMW

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER